REMARKS

I. Preliminary Comments

Applicants note, with gratitude that the previous rejection of claims 1-5 and 7-10 under 35 U.S.C. §102(b) as being anticipated by Brown et al. WO 96/0826 (which corresponds to U.S. 6,060,050) has been withdrawn.

II. Outstanding Rejections

Claims 1-10 and 26-33 are rejected under 35 U.S.C. §112 (second paragraph) as being indefinite with respect to the amount of amylase resistant starch.

Claims 26-28 and 30-33 remain rejected under 35 U.S.C. §102(b) as being anticipated by Brown et al., WO 96/08261 (which corresponds to U.S. 6,060,050).

Claims 6 and 29 relating to treatment of subjects for obesity remain rejected under 35 U.S.C. §103(a) as being obvious over the disclosure of Klor et al., U.S. Patent 5,886,037 in view of Wibert et al., U.S. Patent 5,776,887 and further in view of Seib et al., U.S. Patent 5,855,946.

Claims 1-5, 7-10, 26-28 and 30-33 stand newly rejected under 35 U.S.C. §103(a) as being obvious over the disclosure of Wibert et al., U.S. Patent 5,776,887 and in further view of Seib et al., U.S. Patent 5,855,946.

III. Patentability Arguments

A. The Rejection Under 35 U.S.C. § 112 (second paragraph) Should Be Withdrawn

The rejection on the basis that the claims are indefinite should be withdrawn because those of ordinary skill reading the teachings of the specification would be instructed to measure resistant starch levels by practice of the method of McCleary, Proc. 42nd RACI Cereal Chem. Conf. Christchurch NZ Ed. VJ Humphrey-Taylor pp 304-312 (1992). Even if the specification had not taught use of this particular method (and it did for the reasons set

out below), those of ordinary skill would have known to use this method because it was the method recognized by the AOAC.

Submitted herewith is the Declaration of Ibrahim Abbas, Ph.D. stating that those of ordinary skill were taught by Applicants' specification that the McCleary method be used to determine resistant starch levels. Specifically, the disclosure at para. 0035 teaches:

> "[0035] As used in the specification, the term 'resistant starch' includes those forms defined as RS1, RS2, RS3 and RS4 as defined in Brown, McNaught and Molony (1995) Food Australia 47: 272-275."

Brown et al., Food Australia, (1995) in turn taught that "resistant starch" was defined as "the sum of starch and products of starch degradation not absorbed in the small intestine of healthy individuals" (pg. 272, col. 2 lines 8-14). Brown then cited Prosky et al., J. Assoc. Off. Anal. Chem. 71(5):1017 (1988) as providing "the officially accepted method of the Association of Analytical Chemists" for detecting resistant starch.

The Prosky method was considered the "gold standard" method for the measurement of total dietary fiber (TDF) and was designated AOAC Method 985.29. (See the accompanying Declaration of Ibrahim Abbas Ph.D and McCleary & Rossiter J. AOAC International, 87 No. 3 707-717 (2004) at. 707, col. 2 first full para.) and is the same as the McCleary method of Proc. 42nd RACI Cereal Chem. Conf. Christchurch NZ Ed. VJ Humphrey-Taylor pp 304-312 (1992).

For these reasons, one of ordinary skill in the art would have been directed by the teachings in the specification to use the method of McCleary for determining resistant starch content. Moreover, the references in the application to other publications which direct use of the McCleary method merely reinforce the specific direction already provided in the disclosure to utilize the McCleary method. The fact that other references may utilize different methods to measure resistant starch content is irrelevant where Applicants' already provided instruction as to how it should be measured for purposes of the claims.

For these reasons, the rejection under 35 U.S.C. 112 (second paragraph) should be withdrawn.

B. The Rejection of Claims 26-28 and 30-33 Under 35 U.S.C. §102(b) Over Brown et al., WO 96/08261 Should be Withdrawn.

The rejection of claims 26-28 and 30-33 under 35 U.S.C. §102(b), over Brown WO 96/08261 should be withdrawn in light of the amendments submitted herewith as Brown does not disclose or suggest a method for regulating carbohydrate and fat metabolism comprising replacing at least 15% of the individual's daily carbohydrate intake with resistant starch and at least 10% of the individual's saturated fat intake with unsaturated fat.

C. The Rejection of Claims 6 and 29 Under 35 U.S.C. §103(a) Over Klor et al. In View of Wibert et al., and Seib et al. Should be Withdrawn.

The rejection of claims 6 and 29 directed to the treatment of obesity under 35 U.S.C. §103(a) over of Klor et al., U.S. Patent 5,886,037 in view of Wibert et al., U.S. Patent 5,776,887 and further in view of Seib et al. should be withdrawn because Klor fails to specifically teach the use of resistant starch as acknowledged by the Examiner. While the Examiner argues that Klor "suggests using (1) starch as the carbohydrate component; and (2) a carbohydrate that generates a relatively small rise in plasma lipid or insulin levels" (Action, page 5, lines 15-16) a review of Klor reveals that:

> "In practice this means that carbohydrate sources are used that have low contents of mono- and disaccharides." (col. 4, lines 31-32)

Because resistant starch has no fewer mono- and disaccharides than does non-resistant starch, this teaching of Klor would not have led to the use of resistant starch. Thus,

one of ordinary skill proceeding from the teaching of Klor would not have been motivated to optimize anything with respect to resistant starch.

While Wibert does relate to resistant starch it fails to teach the use of resistant starch at the levels specified in the claims and no reason is presented why the person of ordinary skill would choose to modify Klor so as to choose resistant starch levels foreign to Klor in order to treat obesity.

Klor also fails to teach that replacement of amounts of saturated fat with equal amounts unsaturated fat could provide a method for regulating carbohydrate and fat metabolism as is described in Applicants' invention. While the Examiner notes that Klor's teaching of a range of 55-95% saturated fat overlaps the claimed range of 10-90% such an incomplete overlap is hardly a teaching to always use less than 90% saturated fat (i.e., at least 10% unsaturated fat). This is particularly the case when Klor suggests the use of 95% saturated fat. Accordingly, Klor actually teaches away from another element of Applicants' claims.

As noted previously, the person of ordinary skill in the art would not combine the teachings of Klor and Wibert in any manner, much less to arrive at the composition of the invention, because the two references have an entirely different focus. On the one hand, Klor is directed to a nutritional composition having very large amount of fats most of which are medium chain fatty acids, i.e., saturated fats. Carbohydrates are optional according to the Klor composition. Klor gives no motivation to explore the use of different resistant starches, much less to include a certain amount of resistant starch to replace other forms of carbohydrate.

On the other hand, Wibert is directed to a composition which mostly comprises carbohydrate. However, no specific amount of amylase resistant starch is recommended and there is no motivation to choose any particular fat, whether saturated or unsaturated.

Finally, Seib teaches that Novelose high amylose starch comprises amylase resistant starch but does not teach one to alter the composition of Wibert or to alter the composition of Klor in a manner to arrive at Applicants' invention.

For these reasons the rejection based on the combination of Klor and Wilbert in further combination with Seib should be withdrawn.

D. The Rejection of Claims 1-5, 7-10, 26-28 and 30-33 Under 35 U.S.C. §103(a) Over Wibert et al. In View of Seib et al. Should be Withdrawn.

At the outset it should be noted that the rejection over Wibert and Seib is not an anticipation rejection but one under 35 U.S.C. §103 for obviousness. The obviousness rejection over Wibert in view of Seib should be withdrawn because there is no teaching in Wibert or otherwise which instructs those of skill in the art to use the claimed resistant starch levels of the claims because only one out of eight Wibert examples disclose a proportion of resistant starch to carbohydrate greater than 15% as specified in Applicants' claims. Moreover, there is no teaching in Wibert or Seib to increase the amounts of the composition to the amounts of the claims (and particularly claims 26-28 and 30-33). The argument that those of ordinary skill in the art would have modified the disclosure of Wibert to "attain adequate energy requirements" so as to fall within the scope of the claims is inappropriate in the absence of some concrete teaching that the reference be so modified. The Wibert reference teaches what it teaches. To modify the Wibert disclosure so as to fit the claims now

presented requires an affirmative instruction in Wibert itself or in some other reference as to why Wibert should be so modified.

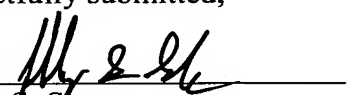
Further, the statement that "[t]he fat component [of Wibert] appears to be essentially limited to unsaturated fat" is incorrect! The examples of Wibert only disclose the use of "vegetable oil" or a "vegetable oil blend." An examination of the specification of Wibert at cols. 3 and 4 reveals a laundry list of vegetable and non-vegetable fats for use in Wibert's compositions including many that are primarily saturated including coconut oil, palm kernel oil, milk fat, and egg yolk lipid. Accordingly, there is no teaching in Wibert or even in Seib (which mainly teaches that high amylose starch contains amylase resistant starch) that would lead one to combine high levels of resistant starch with unsaturated fats in the manner of the invention. For these reasons, the obviousness rejection over Wibert and Seib should be withdrawn.

CONCLUSION

For all of the foregoing reasons, the rejection should now be withdrawn and a notice of allowance of all pending claims is respectfully solicited. Should the Examiner wish to discuss any issues of form or substance in order to expedite allowance of the pending application, she is invited to contact the undersigned attorney at the number indicated below.

Dated: August 25, 2006

Respectfully submitted,

By 

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